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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,406	11/28/2000	Joseph A. Francisco	9632-006-999	7578

20583 7590 12/18/2001

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NEW YORK, NY 100362711

EXAMINER

DAVIS, NATALIE A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/724,406

Applicant(s)

FRANCISCO ET AL.

Examiner

Natalie A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11 and 13-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 8, 11 and 13-19 is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Applicant's amendment filed June 9, 1997 (Paper No: 10) is acknowledged. Accordingly, claims 9-10, 12, and 20-52 are cancelled and 1, 7-8, 11, 13-16 and 19 are amended. Claims 1-8 and 13-19 are being examined.

Information Disclosure Statement

The information disclosure statement filed 17 October 2001 has been considered. A signed copy is attached hereto.

Response to Arguments

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112 1st Withdrawn

Rejection of claims 1-8, 11, and 13-19 under 35 U.S.C.112, second paragraph is withdrawn in view of amendments.

Claim Rejections - 35 USC § 102 Withdrawn

Rejection of claims 1-4, 7-8, 13, 15-16, and 19 under 35 U.S.C. 102(b) is withdrawn in view of amendments and arguments.

Claim Rejections - 35 USC § 103 Withdrawn

Rejection of claims 1-4, 7-8, 13, 15-16, and 19 under 35 U.S.C. 103(a) is withdrawn in view of amendments and arguments.

Claim Rejections - 35 USC § 102

1. Claims 1, 2, 5, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by da Costa, et al., (2000).
2. The claims are drawn to a method of treating Hodgkin's disease by administering an antibody that immunospecifically binds CD30 and a pharmaceutically acceptable carrier.
3. da Costa set forth administration of bispecific antibodies for the treatment of Hodgkin's disease. The humanized, chimeric antibodies specifically target CD30 and CD3 or CD8 or CD16. The antibody is a fusion protein, as it comprises the amino acids of two proteins CD30

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and CD3, CD8, or CD16. Since da Costa, et al. disclose the methods of claim 1, the method of claim 7 is inherent because one would want to determine cytostatic or cytotoxic effect of the treatment. Accordingly, da Costa, et al. anticipate the invention as claimed.

Claim Rejections - 35 USC § 103

4. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over da Costa, et al., (2000) in view of Engert, et al., (1999).
5. da Costa, et al. teach bispecific antibodies for the treatment of Hodgkin's disease. The humanized, chimeric antibodies specifically target CD30 and CD3 or CD8 or CD16. The antibody is a fusion protein, as it comprises the amino acids of two proteins CD30 and CD3, CD8, or CD16. da Costa, et al., does not teach the use of immunotoxins and chemotherapy for the treatment of Hodgkin's disease.
6. Engert et al. teach the treatment of Hodgkin's disease using chemotherapy and immunotoxins constructed with anti-CD30 monoclonal antibodies.
7. It would have been obvious at the time the invention was made to one of ordinary skill in the art to combine the antibodies of da Costa, et al. with the immunotoxins and chemotherapy as taught by Engert, et al. since both are useful in the treatment of Hodgkins disease. In re Kerkhoven, 205 USPQ 1069 (CCPA 1980) states that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to for a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. Furthermore, one would have been motivated to use the method of claim 7 to determine cytostatic or cytotoxic effect of the treatment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, Ph.D.

December 13, 2001


NATALIE A. DAVIS
DIRECTOR
ART UNIT 1642
DECEMBER 13, 2001